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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,128	10/21/2005	Yen Choo	05-278	2651

27890 7590 10/26/2009

STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
10/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,128	CHOO, YEN	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2009 has been entered.

Applicant's supplemental response filed on August 11, 2009 is acknowledged. Claims 1 and 2 have been amended. Claims 1, 2, and 5-16 are under examination.

Rejections Withdrawn

1. In view of Applicant's arguments and lieu of the rejection set forth below, the rejection of claims 1, 2, 5-8, 10 and 12-16 under 35 U.S.C. 102(b) as being anticipated by Nishikawa et al. (Development, 1998; 125: 1747-1757) is withdrawn.

2. In view of Applicant's arguments and in lieu of the rejection set forth below, the rejection of claims 1, 2 and 4-16 under 35 U.S.C. 102(e) as being anticipated by Scholl et al. (U.S.2004/0170965 A1) is withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 5-8, 10 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa et al. (Development, 1998; 125: 1747-1757).

The rejected claims are drawn to a method for determining the effect of a plurality of culture conditions on a cell comprising the steps of: a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; b) subdividing one or more of said groups to create a further set of groups of cell units; c) exposing said further groups to further desired culture conditions; d) repeating steps (b)-(c) iteratively; and e) assessing the effect on a given cell unit of the culture conditions to which is has been exposed.

Nishikawa et al. disclose a method of analyzing cell cultures. The method involves ES cells which were initially maintained on Mitomycin C treated layers in DMEM. The cells were then transferred to gelatin coated culture dishes to remove fibroblasts. Cells were then transferred (subdivided) to each well of IV collagen-coated 6-well cluster dishes and incubated in alpha MEM supplemented with FCS and 2ME. Moreover, Nishikawa et al. disclose that the cultured cells were harvested with a cell dissociation buffer and analyzed for expression of surface markers. The dishes were

coated with gelatin, type I collagen or fibronectin and compared for the ability to support the differentiation of ES cells. Nishikawa et al. disclose that the atmosphere in the chamber holding the cells was 37ºC (see page 1748; Cell Culture). Lastly, Nishikawa et al. disclose that cell layers were prepared in 96-well cluster dishes.

Nishikawa et al. do not specifically disclose repeating steps (b)-(c) iteratively.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Nishikawa et al. by repeating steps (b)-(c) iteratively because repeating the steps creates a highly efficient outcome and allows one to determine which set of conditions would be more effective.

Moreover, the claim would have been obvious because a particular known technique (i.e. repeating steps iteratively) and the technique for improving a particular method was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations. See the recent Board decision *Ex parte Smith,--USPQ2d--*, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396). One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for determining the effect of a plurality of culture conditions on a cell.

4. Claims 1, 2 and 4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholl et al. (U.S.2004/0170965 A1).

The rejected claims are drawn to a method for determining the effect of a plurality of culture conditions on a cell comprising the steps of: a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; b) subdividing one or more of said groups to create a further set of groups of cell units; c) exposing said further groups to further desired culture conditions; d) optionally, repeating steps (b)-(c) iteratively; and e) assessing the effect on a given cell unit of the culture conditions to which is has been exposed.

Scholl et al. disclose a method of cultivating cells. The cell lines were cultured to confluency in sterile polystyrene flasks in EMEM with HEPES, FBS, L-glutamine, and penicillin/streptomycin (see paragraph 0148). Scholl et al. disclose that the cells to be cultured were harvested by first rinsing source cell monolayers with Hank's Balanced Salt Solution (HBSS) without magnesium or calcium. Ten volumes of cell culture medium were added to each trypsinized cell suspension and the cells were repeatedly pipetted in order to produce near-single cell suspensions (see paragraph 0149).

Scholl et al. disclose that the cell mixture monolayers were produced by co-planting two distinct cell types at an equal volume of each diluted cell suspension. The cells were allowed to attach to the well surface by gravity for 30-60 minutes, and the inoculated microtiter plates were incubated for up to three days at 36ºC in 5% CO_2 with 95% relative humidity (see paragraph 0150). Moreover, Scholl et al. disclose that periodically during incubation, single and mixed monolayers were checked for overall viability. The mixed cell culture monolayers were also checked for the ability of the cell lines to co-exist and develop as a single cell sheet, with two distinct cell morphologies,

at an approximately equal density of each cell type. At confluency, the cells were treated with a methylene blue staining solution to fix the cells and stain them a light blue in order to provide contrast for visualization using light microscopy (see paragraph 0151). Scholl et al. disclose that some of the mixed monolayers successfully grew as a mixed cell monolayer adhered to the well surfaces, exhibiting a smooth, evenly distributed monolayer (see paragraph 0152). Scholl et al. disclose that the cell lines are often supplied either in tubes, shell vials, or multi-well plates (e.g., microtiter plates). Lastly, Scholl et al. disclose that after inoculation of the cell line and an appropriate incubation time, confirmation of the presence of HSV in the sample can be accomplished using one or more of the many analytical methods (e.g., immunofluorescence, immunoperoxidase, nucleic acid probes, or substrates for virus-induced reporter genes) (see paragraph 0013).

Scholl et al. do not specifically disclose repeating steps (b)-(c) iteratively.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Scholl et al. by repeating steps (b)-(c) iteratively because repeating the steps creates a highly efficient outcome and allows one to determine which set of conditions would be more effective.

Moreover, the claim would have been obvious because a particular known technique (i.e. repeating steps iteratively) and the technique for improving a particular method was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations. See the recent Board decision *Ex parte Smith,--USPQ2d--*, slip op. at 20, (Bd. Pat. App. & Interf. June

25, 2007) (citing *KSR, 82 USPQ2d* at 1396). One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for determining the effect of a plurality of culture conditions on a cell.

Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
10/23/09

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645